

REMARKS

In reply to the office action mailed September 27, 2005, Applicants amended claims 1, 13, 31, and 37 and cancelled claims 2-4, 32 and 38. Claims 1, 5-15, 31, 33-37 and 39-40 are pending and under examination. Please consider the following remarks.

35 U.S.C. § 112

Claims 1-15 and 31-40 were rejected as failing to satisfy the enablement requirement and written description requirements of 35 U.S.C. § 112, first paragraph. Applicants have amended claims 1 and 31 to require the sugar be either trehalose or sucrose and have amended claim 13 to require the sample to further comprise EDTA. Applicants submit that the amended claims sufficiently enable one skilled in the art to make and use the claimed invention. Moreover, Applicants submit that one skilled in the art would understand that Applicants had possession of the amended claims at the time of filing, and therefore request that this rejection be withdrawn.

Claims 1-15 and 31-40 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants have amended claims 1 and 31 to positively recite a step of storing the sample. One skilled in the art would understand that storing means to keep or put aside for future use. Therefore, Applicants submit that the amended claim recites a positive step of keeping or putting aside for future use, and respectfully requests that the rejection be withdrawn.

The Examiner asserts that the term "substantially free" renders the claims indefinite. However, Applicants submit that one skilled in the art would understand that substantially free of magnesium would mean free to a great extent or degree. Applicants therefore request reconsideration and withdrawal of this rejection.

The Examiner asserts that claim 6 is confusing because the claim recites a UV blocking container containing borosilicate, which itself is UV transparent. Applicants disagree. The recited material borosilicate is not required to be UV blocking, but instead the container as a whole is required to be blocking. One skilled in the art would not be confused by a container that is UV blocking simply because it includes a material, which the Examiner asserts is not. Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner asserts that claim 10 is indefinite for the recitation of the step of lyophilizing DNA because the claim from which it depends requires that the DNA is lyophilized. Applicants disagree. The lyophilized DNA in claim 1 need not be lyophilized by the same party performing the other recited steps, rather, this can be provided already in the lyophilized state, for example by another party. On the other hand, the recitation of a step for lyophilizing the DNA provides an additional positive step in the method of claim 1.

The Examiner asserts that claim 11 is indefinite due to the recitation that the DNA is obtained from the blood of a subject. In contrast to the Examiner's assertion, this recitation is not an additional method step, but instead is a feature describing the DNA itself (i.e., the origin of the blood). The claim does not require obtaining the blood of a subject or extracting the DNA from the blood of the subject, instead, it further describes the DNA. Applicants therefore request reconsideration and withdrawal of this rejection.

The Examiner asserts that claim 15, which requires isolating DNA is adding an additional method step to claim 1. Applicants assert that because claim 15 is dependent from claim 1 and claim 15 positively recites an additional method step, one skilled in the art would understand that claim 15 includes a method step not required by claim 1. The Examiner further asserts that it would not be clear what the DNA would be isolated from. However, Applicants assert that one skilled in the art would understand that DNA could be isolated from any sample in which the DNA is present in sufficient quantity. Therefore, Applicants request reconsideration and withdrawal of the rejection.

The Examiner asserts that claim 35 is indefinite because it is unclear whether the DNA alone would be stored at the recited temperature or whether the entire holding member would be stored at this temperature. Because the DNA is sealed in the container, Applicants assert that one skilled in the art would understand that the holding member itself would also be stored at the recited temperature. Applicants therefore request that this rejection be withdrawn.

35 U.S.C. § 112

Claims 1-15 and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Ando et al (J. Pharm. Sci., 1999), in view of "Kevin Duerinck Genealogy

Page” (March 2001) and CATGee, Ltd. (Product and Company Info, available before Jan. 2004) and in further in view of Cadet et al (Biol. Chem., 1997), Kiefer (U.S. Patent 3,907,586), Labconco (“A Guide to Freeze Drying for the Laboratory” © 1997) bowman et al (WO 03/031935) and Gilbert et al (Current Protocols in Human Genetics, 1998).

The Examiner asserts that Ando teaches a method for providing a genetic sample comprising lyophilized DNA samples that are stable for storage. However, Ando discloses that lyophilization of the microsphere (i.e., the microsphere of plasmid DNA) nicked the DNA, and therefore Ando developed an alternative method of processing the DNA. Accordingly, one skilled in the art reading Ando would not use lyophilized DNA as recited in the claims, but instead would use DNA prepared by the cryopreparation technique described therein. Moreover, the failure to positively recite an element in a reference does not preclude one skilled in the art, when reading the reference to understand that element would be present, especially in instances where one skilled in the art would expect the presence of the element in, for example components of the recited invention. For example, in the case of magnesium, as recited in the pending claims, Applicants assert that Ando's failure to recite the presence of magnesium does not teach that the product be substantially free of magnesium because magnesium and other trace elements are known in the art to be associated with DNA.

None of the other cited references provide the teachings missing from Ando, nor are they relied upon for such. Accordingly, Applicants assert that the combined references fail to teach or suggest each element of the claimed invention and request that the rejection be withdrawn.

Claims 1-12, 14-15, and 31-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Volkin et al (US 2002/0156037) in view of “Kevin Duerinck Genealogy Page” (March 2001) and CATGee, Ltd. (Product and Company Info, available before Jan. 2004) and in further in view of Cadet et al (Biol. Chem., 1997), Kiefer (U.S. Patent 3,907,586), Labconco (“A Guide to Freeze Drying for the Laboratory” © 1997) bowman et al (WO 03/031935) and Gilbert et al (Current Protocols in Human Genetics, 1998).

As with Ando above, Applicants assert that the failure to positively recite an element in a reference does not preclude one skilled in the art, when reading the reference, to understand that

element would be present. For example, in the case of magnesium as recited in the pending claims, Applicants assert that Volkin's failure to recite the presence of magnesium does not teach that the product be substantially free of magnesium for the same reasons that this would not be suggested by Ando.

None of the other cited references provide the teachings missing from Ando, nor are they relied upon for such. Accordingly, Applicants assert that the combined references fail to teach or suggest each element of the claimed invention and request that the rejection be withdrawn.

Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050, referencing attorney docket no. 16270-003001.

Respectfully submitted,

Date: MARCH 27, 2006

Jeffie A. Kopczynski
JEFFIE A. KOPCZYNSKI, REG. NO. 56,395, FOR
Catherine M. McCarty
Reg. No. 54,301

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906